REMARKS/ARGUMENTS

Status of claims

After entry of this amendment, claims 5-7 and 18-19 are pending in the present application. Claim 5 has been amended to refer to *Archeoglobus fulgidis,* support for this amendment is replete throughout the specification and is found, for example, at page 5, line 4. Claim 5 has been amended to refer explicitly to the activity of the enzyme under the incubation and temperature conditions of a polymerase chain reaction. Support for the claim amendment is found on page 5, line 8. New claim 18 finds support at page 13, lines 13-16 and in the sequence listing. Support for claim 19 is found in the sequence listing.

Claims 5-7 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description. Claims 5-7 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Zhu *et al. Nucleic Acids Research* 19:2511 (1991). Claims 5-7 are also rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Barnes *et al.* (US 2003/0049643 A1). Each of the rejections will be addressed in the order in which they were raised.

Rejection under 35 U.S.C. § 112, first paragraph

In rejecting claims 5-7 for allegedly lacking written description, the Examiner acknowledges that the thermostable enzyme exhibiting 3'-5' exonuclease activity but essentially no DNA polymerase from *Archeoglobus fulgidis* is adequately described (*see* Office Action, page 5, first sentence). To expedite prosecution applicants have amended claim 5 to refer explicitly to the *Archeoglobus fulgidis* enzyme. Applicants specifically reserve the right to pursue the original scope of claim 5 in one or more subsequent applications.

Applicants note that claim 5 encompasses variants of the exemplified *Archeoglobus fulgidis* sequence, SEQ ID NO: 21. In the Office Action, the Examiner states that sequence information is required to meet the written description requirement (*see* Office Action, page 3, last paragraph). Applicants respectfully submit that this is not a correct statement of the law.

It is well settled that the written description requirement is satisfied when the specification describes the claimed invention in sufficient detail that one of skill in the art can reasonably conclude that the inventor had possession of the claimed invention (*see, e.g.*, MPEP § 2163(I), citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). Moreover, the Federal Circuit has made it clear that "[I]it is not correct . . . that all functional descriptions of genetic material fail to meet the written description requirement." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324, 63USPQ2d 1609, 1613 (Fed. Cir. 2002). See also *Moba B.V. v. Diamond Automation Inc.*, 325 F.3d 1306, 1320, 66 USPQ2d 1429, 1439 (CA FC 2003) (stating "[m]ore recently, in *Enzo Biochem*, we clarified that *Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, ***the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.*** *Amgen*, 314 F.3d at 1332") (emphasis added).

In the present case, applicants provide a particular, known structure (SEQ ID NO: 21) to which is correlated to a known function (thermostable exonuclease III activity). As noted in the first full paragraph of page 2 of the specification, several thermostable exonulceases were known in the art, at the time the application was filed. Indeed these enzymes were well-studied and many of them were commercially available at the time of the invention (*see* specification page 2, first full paragraph). Based on the teaching in the specification and knowledge in the art, one of skill would recognize that variants of the disclosed sequence (*e.g.*, allelic variants) exist and could easily correlate their structure with the disclosed function. Moreover, one of skill could readily prepare such polynucleotides from *A. fulgidis* DNA using the present disclosure and knowledge in the art at the time of the invention.

In light of the above, applicants believe the rejection is overcome and should be withdrawn.

Rejection under 35 U.S.C. § 102(b)

The rejection of claims 5-7 for allegedly being anticipated by Zhu *et al.* is traversed in part and overcome in part as explained below. In the Office Action, the Examiner

states that earlier arguments pointing out that the enzymes of Zhu *et al.* are inactivated at 95°C cannot be accepted because the enzymes of the invention are active at temperatures of 70°C and above. Applicants note, however, that the claims are directed to a thermostable enzyme, which in the context of the present invention means that the enzyme is functional under PCR conditions. To clarify this aspect of the enzyme, claim 5 has been amended to refer to the fact that the enzyme is active under incubation and temperature conditions of a polymerase chain reaction. Support for the claim amendment is discussed above.

Zhu *et al.* teaches the use of exonuclease III to remove contaminating dsDNA in a PCR reaction mixture before the reaction is started. This reference specifically teaches that an advantage of the exonuclease III used there is that it is denatured when the mixture is heated to 95°C during the PCR process (*see* page 2511, second column). Thus, thermostability is actually taught against in this reference.

In light of the above, Zhu *et al.* neither disclose nor suggest the claimed invention. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The rejection of claims 5-7 for allegedly being obvious over Barnes *et al.* is respectfully traversed in part and overcome in part by the above-amended claims. Barnes *et al.* is cited for teaching use of an exonuclease in combination with a DNA polymerase, but fails to teach the use of an exonuclease that lacks DNA polymerase activity. The Examiner alleges that use of such an exonuclease is obvious in view of the other teaching in the Barnes *et al.* reference.

The pending claims are directed to thermostable *A. fulgidis* enzymes. The only exonucleases taught in Barnes *et al.* are those from *Pyrococcus furiosus*, *Thermotoga maritima*, and *Thermococcus litoralis*. The Examiner has identified nothing in this reference that discloses or suggests the use of *A. fulgidis* enzymes. In the absence of a showing that these enzymes are disclosed or suggested by Barnes *et al.*, alone or in combination with any other prior art reference, the rejection should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

Kevin Bastian
Reg. No. 34,774

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments
KLB:klb
60284484 v1